

QUANTITY LIMIT PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

PRUDOXIN
(doxepin)

ZONALON
(doxepin)

Status: CVS Caremark® Criteria

Type: Quantity Limit; Post Limit Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Prudoxin

Prudoxin cream is indicated for the short-term (up to 8 days) management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus.

Zonalon

Zonalon cream is indicated for the short-term (up to 8 days) management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus.

INITIAL QUANTITY LIMIT**

INITIAL LIMIT QUANTITY

Limits should accumulate across all drugs and strengths up to highest quantity listed depending on the order the claims are processed.

<u>Drug</u>	<u>1 Month Limit*</u>	<u>3 Month Limit*</u>
Prudoxin (doxepin)	45 grams / 25 days	Does Not Apply*
Zonalon (doxepin)	45 grams / 25 days	Does Not Apply*

* The duration of 25 days is used for a 30-day fill period to allow time for refill processing.

* **These drugs are for short-term acute use; therefore, the mail limit will be the same as the retail limit. The intent is for prescriptions of the requested drug to be filled one month at a time, even if filled at mail order; there should be no 3 month supplies filled.**

**If the patient is requesting more than the initial quantity limit, the claim will reject with a message indicating that a prior authorization is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for the management of moderate pruritus in an adult patient with atopic dermatitis or lichen simplex chronicus

AND

- The requested drug being prescribed for short-term use (up to 8 days)

Quantity limits apply.

90 grams per 25 days*, 3 month limit Does Not Apply*

Prudoxin, Zonalon Limit, Post PA Policy UDR 07-2023.docx

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Duration of Approval (DOA):

- 3765-HJ: DOA: 3 months

REFERENCES

1. Prudoxin [package insert]. Newtown, PA: Prestium Pharma, Inc.; June 2017.
2. Zonalon [package insert]. Newtown, PA: Prestium Pharma, Inc.; June 2017.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. <https://online.lexi.com>.; Accessed June 7, 2023.
4. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 06/07/2023).
5. Eichenfield L, Tom W, Berger T, et al. Guidelines of Care for the Management of Atopic Dermatitis Section 2. Management and treatment of atopic dermatitis with topical therapies. *J Am Acad Dermatol* 2014; 71:116-32.

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